Notice of Allowability	Application No.	Applicant(s)	
	10/668,071	ABBOUD, SEMAAN	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.

2. ☒ The allowed claim(s) is/are *4-9 and 2-3 [renumbered as 1-8]*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 2/20/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

JOHN PAK
PRIMARY EXAMINER
GROUP 1600

Claims 1-16 are pending in this application.

Restriction Requirement & Election Without Traverse

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to a method of cleansing a colon in preparation for a colonoscopy, classified in class 424, subclasses 601, 602, 606, 680, 722, class 514, subclasses 277, 619, 867, 872, 892.

II. Claims 10-16, drawn to a "combination" of compositions for cleansing a colon, classified in class 424, subclasses 601, 602, 606, 680, 722, class 514, subclasses 277, 619.

Although the two inventions may at first blush appear to be related as composition and method of use inventions, the "combination" claims actually carry a far broader scope. A combination could read on some sort of a method concept, a kit, or a mere combination or display of compositions sitting on a shelf at a pharmacy store – there is no physical proximity or link associated with the claimed "combination." Therefore, the two inventions are not related and the two inventions are independent and distinct from one another. The distinctness of the composition is established by the fact that the composition can be used in a materially different process, such as in treating a patient for constipation, nausea or vomiting.

There would be undue burden in having to search and examine more than one invention group. The prior art related to gastro-intestinal agents is quite extensive and a

search for just one of the inventions would already be of sufficient burden. Further, the scope of components such as "a phosphorus containing composition" and "sodium" for physiological therapies make it especially challenging due to the common presence of such components in pharmaceuticals. The search for the combination invention would involve a broad interpretation of what is meant by "combination," and such a search would necessitate searching for product lines and product links that may have nothing to do with a method of preparing for a colonoscopy.

Therefore, for reasons of independence or distinctness, and undue burden, the restriction requirement as set forth above is deemed to be proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised

that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During telephone conversations with Mr. Pequignot on 9/29/2005 and 9/30/2005 an election was made **without** traverse to prosecute the invention of I, claims 1-9. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Pequignot on 9/30/2005.

Cancel claims 1 and 10-16.

Claim 2 (Currently amended). The method according to claim 4, wherein said combination of compositions, when ingested by a patient having a colon, is sufficient to

trigger a physiological response, including peristalsis of the colon, whereby the colon is subsequently adequately cleansed for a colonoscopy procedure.

Claim 3 (Currently amended). The method according to claim 4, wherein said phosphorus containing composition is selected from the group consisting of phosphate, potassium phosphate, monobasic sodium phosphate, and dibasic sodium phosphate

Claim 4 (Currently amended). A method of cleansing a colon in preparation for a colonoscopy comprising ingesting a combination of compositions in pharmaceutically effective amounts, wherein said combination of compositions is ingested in a series of sequential doses comprising:

a) a first dose comprising bisacodyl;

b) a second dose comprising a combination of bisacodyl, metoclopramide, a phosphorus containing composition, and sodium;

c) a third dose comprising bisacodyl, a phosphorus containing composition, and sodium; and

d) a fourth dose comprising metoclopramide.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The claimed invention, as presently amended, is directed to a method of cleansing a colon in preparation for a colonoscopy procedure. The method comprises a

series of sequential doses, the first dose comprising bisacodyl, the second dose comprising bisacodyl, metoclopramide, phosphorus containing composition, and sodium, the third doses comprising bisacodyl, phosphorus containing composition, and sodium, and the fourth dose comprising metoclopramide.

While each of the individual agents are separately known in the colonic cleansing or colonic evacuant art, their specific combination in the claimed sequence is neither disclosed nor fairly suggested by the prior art.

Three of the most widely accepted bowel preparations for colonoscopy are (1) balanced electrolyte lavage solution (PEG), (2) small-volume oral sodium phosphate based solution, and (3) sodium phosphate based pill/tablet. There are many other known preparations for similar utility (see e.g., **Drug Facts and Comparisons**, pages 1235-1237). However, it is known that each category of such agents has different side effects and different indications (**Medline abstract 1999113696**), and the prior art does not fairly suggest the presently claimed method of sequentially ingesting the combination of multiple compositions.

Zmora et al. (2003) disclose results from a survey of members of the American Society of Colon and Rectal Surgeons (page 150). Sodium phosphate and/or PEG are the most widely used bowel preparations, used by 93% of the respondents, with magnesium citrate and "other" accounting for 6% and 1%, respectively (page 152, Figure 3).

Tasci et al. (2003) evaluate 7 different bowel cleansing procedures: (1) sennoside calcium; (2) PEG electrolyte solution; (3) sodium phosphate, monobasic and dibasic, in solution form, 90 ml 1 day prior to colonoscopy; (4) sodium phosphate solution, 90 ml 1 day prior and 45 ml 5 hours prior to colonoscopy; (5) sodium phosphate solution; 45 ml 1 day prior and 90 ml 5 hours prior to colonoscopy; (6) sodium phosphate solution + cisapride; and (7) sodium phosphate solution + domperidone (see pages 18-19).

Toledo et al. (2001) disclose that "patient compliance is enhanced by simplicity and well-tolerated methods" of colon cleansing (abstract). Metoclopramide (page 606, right column), phosphates and bisacodyl (Table 2 on page 607) are disclosed, but such a disclosure is far from disclosing any specific sequential dosing of the presently claimed invention. **Pinfield et al.** (1999) disclose bisacodyl tablets combined with a phosphate enema for children (Regimen 2 on pages 181-182).

In summary, while there are many different agents that could be used for cleansing a colon in preparation for a colonoscopy, 97% of colon and rectal surgeons from one survey utilize sodium phosphate or PEG. Further, while each of the compositions utilized in the presently claimed invention is individually known for use in colon cleansing related utility, their combined use as claimed here is far from disclosed or suggested by the prior art. In fact, the prior art appears to teach away from applicant's claimed sequential dosing method, because the ordinary skilled artisans in

this field, when evaluating alternative colonic cleansing preparations, fail to even consider the combination of sequential doses, as claimed here (see Zmora et al., Tasci et al., Toledo et al.). Moreover, since the state of the art finds that simplicity in a regimen enhances patient compliance (Toledo et al.), the sequential dosing of four doses of multiple combinations of compositions (instant invention) is not seen to be fairly suggested.

For the foregoing reasons, the claimed invention *as a whole* is deemed to be patentable over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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